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EXAMINER

VENKAT, J

ART UNIT PAPER NUMBER

1502

DATE MAILED: 11/27/95

RESE TAYLOR
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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 8/25/95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1-9, 13 are pending in the application.

Of the above, claims are withdrawn from consideration.

2. ☒ Claims 10-12 have been cancelled.

3. ☒ Claims 13 are allowed.

4. ☒ Claims 1-9 are rejected.

5. ☐ Claims are objected to.

6. ☐ Claims are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

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Receipt is acknowledged of declaration and amendment a both filed on 8/25/95.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-12 have been cancelled and claim 13 has been added as per applicants amendment dated 8/25/95, claims 1-9 and 13 are pending in the application.

The following new ground of rejection is necessitated by the amendment.

Claims 4-6 and 8-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above claims lack antecedent basis for "or compound metabolized to nicotinic acid by the body"

The declaration filed on 8/25/95 under 37 C.F.R. § 1.131 has been considered but is ineffective to overcome the U.S. Patent 5,268,181 reference.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country prior to the effective date of the U.S. Patent '181 reference.

1. Exhibit A deals with a "single-blind placebo controlled pilot study comparing the effect of once-a-day versus twice-a-day dosing

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of serum lipids" where as the claims are drawn to "method of treating hyperlipidemia compound nicotinic acid carrier with pharmaceutically acceptable carrier

2. The study did not show any results to the reduction of total and LDL cholesterol, triglycerides and Lp, with an increase in HDL cholesterol.

3. The study under design showed intake of 4 tablets or 2 tablets where as claim 6 is to formulation or tablet.

4. There are not test results in the declaration.

5. Note that the purpose of study is for a different "method" and not related to the instant claimed method.

6. There is no record of PVP + niacin + lubricating agents.

Based upon the above foregoing facts 102(e) rejection is deemed proper.

Claim 13 is allowed.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE

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EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Venkat whose telephone number is (703) 308-2439.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.


JYOTHSAN VENKAT, Ph.D
PRIMARY EXAMINER
GROUP 1500

J. Venkat:pdw
November 21, 1995
703-308-2351